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association of antidepressants such as fluoxetine and suicidality. (Dkt. #129). Therefore, plaintiff asserts that summary judgment is not appropriate.

For the reasons set forth below, the Court agrees with plaintiff and DENIES defendants' motion for summary judgment.

II. DISCUSSION

A. Background

Plaintiff, Yvonne A'Rae Laisure-Radke, brings this lawsuit on behalf of herself and as individual representative of her late husband's estate. She alleges that her husband, Douglas Radke, committed suicide while under the influence of the antidepressant drug fluoxetine, which is the generic version of Eli Lilly's Prozac. Defendants manufacture, distribute and market the generic drug in question in this case. Plaintiff essentially asserts that defendants were aware of an increased risk of suicidality in users of the class of antidepressant drugs within which Fluoxetine lies, known as selective serotonin reuptake inhibitors ("SSRIs"), well before the death of Ms. Laisure-Radke's husband, but did not adequately warn of that risk.

Douglas Radke was a correctional officer in Whatcom County, Washington. Throughout his life he struggled with alcoholism and depression, although he had been sober for the last 17 months of his life. At the time of his death, Mr. Radke was married to plaintiff, and supported two children from his previous marriage to Eva Browning.

In March of 2000, Mr. Radke began individual counseling sessions for marital problems and other stresses in his life with Priscilla Tragessor Hone, Ph.D., a chemical dependency specialist. He stopped drinking in June of 2000. Although he apparently experienced intense cravings, he remained sober, with the exception of one beer on New Year's Eve, until he died.

On October 26, 2000, Mr. Radke began counseling sessions with Michael Praetzel, a clinical social worker. After seeing Mr. Radke again on October 31, 2000, Mr. Praetzel diagnosed him with

general anxiety disorder, depression and high levels of stress.

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psychologist. Dr. Portman referred Mr. Radke to an intensive outpatient program for his alcoholism.

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During that time, it appears that Mr. Radke was also taking Atenolol and Wellbutrin for his anxiety

On January 31, 2001, Mr. Radke was assessed for his alcoholism by Dr. Portman, a

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and depression.

either one.

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On January 23, 2001, during a doctor's appointment with Dr. Moore, who had been Mr. Radke's physician since 1991, Mr. Radke reported that he believed he was experiencing sweat outbreaks and shakes as side effects of the medication he was taking. Dr. Moore discontinued Mr. Radke's prescriptions for Atenolol and Wellbutrin, and prescribed Prozac. He also advised Mr. Radke to seek assistance from a psychiatrist, recommending two choices. Mr. Radke apparently never saw

On February 8, 2001, Mr. Radke saw Dr. Moore for a follow-up visit for his depression. Dr. Moore continued his prescription for Prozac.

On March 22, 2001, Mr. Radke saw Mr. Praetzel, and apparently told him that he felt more balanced on Prozac. However, he also reported that he had been having homicidal tendencies. As a result, Mr. Praetzel also recommended that Mr. Radke see one of the two psychiatrists Dr. Moore had recommended, but again Mr. Radke failed to do so.

On April 16, 2001, Dr. Moore increased Mr. Radke's Prozac prescription from 20 mg once a day to 40 mg once a day. That was Mr. Radke's last visit to Dr. Moore.

On August 2, 2001, the Food and Drug Administration ("FDA") approved defendants' generic fluoxetine 40 mg capsules. The approved label included information relating to suicide. Under the "Precautions" section, it read:

> Suicide – The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for fluoxetine should be written for the smallest quantity consistent with good patient management in order

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to reduce the risk of overdose.

In addition, "suicide attempt" was listed as an adverse event reported during clinical trials.

On August 30, 2001, Mr. Radke refilled his Prozac prescription and received defendants' generic fluoxetine 40 mg capsules. Shortly thereafter, he began voicing thoughts of suicide. Plaintiff, Mr. Praetzel, Dr. Moore, Mr. Radke's children and other members of Mr. Radke's family all testify that he had never voiced any notions of suicide or suicidal ideation prior to that time period.

On October 8, 2001, Mr. Radke saw a counselor at Chambers and Wells. That counselor apparently recommended that Mr. Radke see a psychiatrist. Again, Mr. Radke chose not to do so.

On October 11, 2001, Mr. Radke refilled his Prozac prescription and received generic fluoxetine.

On November 15, 2001, Mr. Radke filled his Prozac prescription and received generic fluoxetine.

On November 18, 2001, Mr. Radke packed some clothes and left the state. Three days later, he apparently called his brother and told him that he was headed east, with no particular destination in mind, and that he intended to get a job and send money home for child support.

On November 27, 2001, a rancher in Kansas found Mr. Radke's car at the entrance to his pasture. Tragically, sometime earlier, Mr. Radke had climbed into the trunk and shot himself in the head. He left notes for "the person that found him," his wife, his children, his parents, and one of his former colleagues, explaining that he had struggled with mental illness, he was hearing voices that seemed to control him, and he had given all he could but it just wasn't enough. The instant lawsuit followed.

In her Complaint, plaintiff makes three claims for relief, including:

FIRST: All defendants are jointly and severally liable for marketing a defective product with inadequate and/or legally defective labeling and for marketing with misrepresentations

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SECOND: Defendants' conduct is unreasonable, or negligent, and was a proximate cause of Plaintiff's decedent's injuries and death. The manufacturers were all negligent for failing to warn, failing to test or otherwise to investigate the association between FLUOXETINE, akathisia, psychosis, and suicide, and for misrepresenting and over-promoting "FLUOXETINE."

THIRD: Defendants' [sic] are liable because "FLUOXETINE" was defective and potentially harmful to its consumers/users, including Plaintiff [sic] decedent, and because adequate warnings were not provided with the product or after manufacture, and as such was unsafe to an extent beyond that contemplated by an ordinary user and consumer set forth in RCW 7.72.030.

(Dkt. #39 at 11).

B. Common Law Negligence Claims

As a threshold matter, the Court addresses defendants' argument that product-related, common law liability claims filed after July 26, 1981, are preempted by the WPLA. Defendants assert that plaintiff's claims for negligent failure to warn, negligent failure to test or otherwise investigate the association between fluoxetine, akathasia, psychosis, and suicide, negligent misrepresentation and negligent over promotion, which all appear to be based on common law negligence theories, must be dismissed as a matter of law. Defendants further assert that plaintiff's claim for negligent marketing of a defective product with inadequate and/or legally defective labeling, which also appears to be based on a common law theory of negligence, should also be dismissed as a matter of law. The Court agrees.

As the Supreme Court of Washington explained in *Washington Water Power Co. v. Graybar Elec. Co.*, 112 Wn. 2d 847, 850-55(1989), the WPLA preempts traditional common law remedies for product-related harms. Such "[a] claim previously based on negligence is within the definition of a product liability claim. Since this present cause of action is predicated upon a failure to warn by a product manufacturer, any negligence cause of action therefor is now preempted by the [W]PLA. Therefore, this product liability claim cannot be maintained on a common law negligence theory." *Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 323 (1993).

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Accordingly, the Court DISMISSES plaintiff's claims for negligent failure to warn, negligent failure to test or otherwise investigate the association between fluoxetine, akathasia, psychosis, and suicide, negligent misrepresentation, negligent over promotion and negligent marketing of a defective product with inadequate and/or legally defective labeling, to the extent that they are based on a common law theory of negligence.

C. Washington State Product Liability Claims

The Court now turns to defendants' arguments pertaining to claims arising under the WPLA.

1. Defendant's Compliance with Labeling Regulations

Defendants first argue that plaintiff's failure to warn claim should be dismissed because defendants were forbidden to alter their label from that of the reference listed drug, Prozac. The Court has already addressed this argument in its Order on defendants' motion for summary judgment based on the preemption doctrine. (Dkt. #165). In that motion, relying on 21 U.S.C. § 355(j)(2)(A)(v) and 21 C.F.R. § 314.94(a)(8), defendants argued that a "generic manufacturer simply cannot deviate its labeling from that of a reference listed drug." (Dkt. #113 at 23). The Court agreed that as part of its abbreviated new drug application ("ANDA"), a generic manufacturer must submit information that its proposed label is identical to that of the reference listed drug. (Dkt. #165 at 5). However, the Court found defendants' argument flawed with respect to manufacturers that hold approved ANDAs, determining that once the ANDA is approved, generic manufacturers have the same power and duty to add or strengthen their warnings, as do the manufacturers of pioneer drugs, and therefore, the same liability. (Dkt. #165 at 6-7). The Court further found that once a generic drug manufacturer holds an approved ANDA for a particular product, it can add or strengthen a contraindication, warning, precaution or adverse reaction at any time without prior FDA approval. (Dkt. #165 at 8). Thus, the Court again denies defendants' motion for summary judgment on that basis.

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2. RCW 7.72.030(2)

Before addressing plaintiff's product liability claims under RCW 7.72.030(1), the Court addresses plaintiff's apparent argument that a strict liability standard should apply to this case because RCW 7.72.030(2) mandates such a standard. RCW 7.72.030 (2) provides:

- (2) A product manufacturer is subject to strict liability to a claimant if the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction or not reasonably safe because it did not conform to the manufacturer's express warranty or to the implied warranties under Title 62A RCW.
 - (a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.
 - (b) A product does not conform to the express warranty of the manufacturer if it is made part of the basis of the bargain and relates to a material fact or facts concerning the product and the express warranty proved to be untrue.
 - (c) Whether or not a product conforms to an implied warranty created under Title 62A RCW shall be determined under that title.

RCW 7.72.030(2)(a)-(c). It is not clear to this Court how that section applies to the instant case.

Nothing in plaintiff's First Amended Complaint indicates that plaintiff alleges a breach of any warranty, express or implied. (*See* Dkt. #39). Indeed, in her Response to the instant motion, plaintiff fails to identify any alleged breach of warranty either express or implied. The Court recognizes that under Title 62A, implied warranties include the implied warranty of merchantability, and that the warranty of merchantability encompasses considerations of the adequacy of the package and label. RCW 62A.2.314(2); *Hue v. Farmboy Spray Co.*, 127 Wn. 2d 67, 89-90 (1995). However, if plaintiff believes she has raised a breach of implied warranty claim, she has completely failed to indicate which implied warranty was not honored by defendants, nor has she alleged any facts in support of such a claim, and this Court will not presume to raise a claim that plaintiff failed to allege. *See Hue*, 127 Wn. 2d at 90 (explaining that the court cannot make such a presumption). Accordingly, the Court rejects ORDER

plaintiff's arguments based on RCW 7.72.030(2).

3. Inadequate Labeling/Failure to Warn Claims

Defendants next argue that, with respect to plantiff's WPLA failure to warn claim, plaintiff has failed to demonstrate proximate cause, as she has failed to establish any causal link between the alleged failure to warn and her alleged injuries. Plaintiff responds that a question of material fact exists as to whether the warnings defendants provided were adequate, and whether defendants acted reasonably in light of the information known about increased risk of suicidality and SSRIs at the time of manufacture.

RCW 7.72.030 states in pertinent part:

A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.

- (b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.
- (c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.
- RCW 7.72.030(1)(b). It appears from the Third Claim for Relief set forth in plaintiff's First Amended Complaint that both subparagraph (b) and (c) are alleged bases for her claims. (Dkt. #39 at 11) (alleging that adequate warnings were not provided with the product or after manufacture).

Until recently, it appeared that Washington courts applied a strict liability standard to all failure

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to warn and inadequate warning claims brought under RCW 7.72.030(1)(b). Ayers v. Johnson & Johnson Baby Prods. Co., 117 Wn.2d 747, 763 (1991); Anderson v. Weslo, Inc., et al., 70 Wn. App. 829, 838 (1995). The Ninth Circuit Court of Appeals had also determined that such claims would likely be examined under a strict liability standard. Transue v. Aesthetech Corp., et al., 341 F.3d 911, 918-19 (9th Cir. 2003). However, in Estate of LaMontagne v. Bristol Meyers Squibb, et al., 127 Wn. App. 335 (2005), the Washington State Court of Appeals firmly stated that "[w]hether a prescription drug manufacturer provides adequate warning to physicians is governed by the negligence standard under the Restatement (Second) of Torts § 402A, cmt. k (1965)," thereby distinguishing prescription drug products from the consumer products examined in Ayers and Andserson, supra. LaMontagne, 127 Wn. App. at 343 (explaining that comment k, adopted by the Washington Supreme Court in Terhune v. A. H. Robins, Co., 90 Wn.2d 9, 12-13 (1978), is an exception to strict liability for unavoidably unsafe products); see also Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493 (2000); Young v. Key Pharmaceuticals, 130 Wn. 2d 160, 166-67 (1996). In Terhune, the court also made clear that where the product can be sold only under prescription, the duty to warn runs only to the physician, not to the ultimate consumer. Terhune, 90 Wn.2d at 13, 17. Thus, the Court first addresses whether defendants' label provided warnings that were adequate as a matter of law. Like RCW 7.72.030(1), comment k imposes a duty on a drug manufacturer to warn of the

Like RCW 7.72.030(1), comment k imposes a duty on a drug manufacturer to warn of the known dangers and risks associated with prescription drugs. It states:

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper

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¹ The state Supreme Court has distinguished subparagraph (b) from subparagraph (c), "which clearly embraces a negligence standard." *Ayers*, 117 Wn.2d at 765.

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directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965). The comment further provides that a warning for a prescription drug may be adequate as a matter of law if it provides specific and detailed information about the risks of using the drug. *Id*.

To determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. *LaMontagne*, 127 Wn. App. at 344. The court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in taking the prescription drug. *Martin v. Hacker*, 83 N.Y.2d 1, 10-11, 628 N.E.2d 1308, 607 N.Y.S.2d 598 (1993); *cf. Little v. PPG Indus., Inc.*, 92 Wn.2d 118 (1979) (determining the adequacy of a warning by examining whether the warning sufficiently attracted the attention of the product users and informed them of the dangers of the product).

In addition, in addressing whether a drug manufacturer has met its duty to give adequate warnings for prescription drugs, Washington has adopted the "learned intermediary" doctrine. *LaMontagne*, 127 Wn. App. at 345; *Terhune*, 90 Wn.2d at 13-14. Under the learned intermediary doctrine a drug manufacturer satisfies its duty "to warn of dangers involved in use of a product . . . if it gives adequate warning to the physician who prescribes it." *Id.* at 13. The *Terhune* Court explained that when a product that is available only through prescription

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is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

Terhune, 90 Wn.2d at 14.

Finally, because FDA regulations provide only the minimum requirements for drug manufacturers, compliance with those regulations does not necessarily establish that the warnings at issue were adequate. *See Wash. State Physicians Ins. Exchange & Assoc. v. Fisons Corp.*, 122 Wn.2d 299, 328-29 (1993).

In the instant case, defendants provided the following suicide-related warnings on their label.

Under the "Precautions" section, it read:

<u>Suicide</u> – The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for fluoxetine should be written for the smallest quantity consistent with good patient management in order to reduce the risk of overdose.

In addition, "suicide attempt" was listed as an adverse event reported during clinical trials. Plaintiff argues that in light of the information available at the time of manufacture, and after manufacture, there should have been a stronger warning, such as the Black Box warning now required on all SSRIs, which indicates an increased risk for suicidal behavior in children and adolescents who are being treated with those drugs.

Defendants first argue that plaintiff's claim fails because she has not articulated what warning she believes would have been adequate. The Court finds this argument without basis. In *Ayers*, *supra*, the Supreme Court of Washington rejected a nearly identical argument, holding "that the language of RCW 7.72.030(1)(b) does not require a claimant to establish the exact wording of the alternative warning. The statute's requirement . . . is satisfied if the claimant specifies the substance of the warning." *Ayers*, 117 Wn.2d at 756. Plaintiff has done so in the instant case.

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Defendants next argue plaintiff has failed to specify any new information that defendants learned or should have learned after manufacture, and that even if there was such information, defendants could not have provided a stronger warning based on such information within the four month window it had between the date it was approved for marketing and the date that Mr. Radke committed suicide. Defendants assert that for these reasons, plaintiff's claims fail as a matter of law. The Court disagrees.

First, the Court has already rejected defendants' inability to warn without prior FDA approval argument above, and, in more detail, in its previous Order denying defendants' motion for summary judgment based on the preemption doctrine. Second, plaintiff has provided expert testimony supported by numerous medical journal articles, case studies, and other documents, raising a genuine issue of material fact as to whether defendants were aware or should have been aware of an increased risk of suicidality in patients using SSRIs. Indeed, defendants themselves note that starting in 1991, after Prozac was approved for market, the FDA began receiving requests for warnings of such a risk, which eventually led to further investigation by the FDA and SSRI manufacturers. Moreover, Dr. Moore testified that he was aware of such increased risk as early as the late 80s or early 90s, and warned his patients of that risk at the time. For these reasons, the Court finds that defendants' label cannot be deemed adequate as a matter of law, and that the adequacy question is more appropriately resolved by the jury.

The Court next addresses the issue of proximate cause, which can be resolved as a matter of law when no reasonable persons would differ. *Lunt v. Mt. Spokane Skiing Corp.*, 62 Wn. App. 353, 362, *review denied*, 118 Wn.2d 1007 (1991). To show proximate causation, the plaintiff must show both cause in fact and legal causation. *Ayers*, 117 Wn.2d at 753; *Baughn v. Honda Motor Co.*, 107 Wn.2d 127, 142 (1986). "Cause in fact refers to the 'but for' consequences of an act – the physical connection between an act and an injury." *Hartley v. State*, 103 Wn.2d 768, 778 (1985). Legal

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causation depends on considerations of "logic, common sense, justice, policy, and precedent." *King v. Seattle*, 84 Wn.2d 239, 250 (1974). It involves the "determination of whether liability *should* attach as a matter of law given the existence of cause in fact." *Hartley*, 103 Wn.2d at 779 (emphasis in original).

Cause in fact is usually a jury question. Baughn, 107 Wn.2d at 142. However, it may become a question of law "when the facts are undisputed and inferences therefrom are plain and incapable of reasonable doubt or differences of opinion. . . " Id. Defendants argue that plaintiff fails to appreciate the importance of the learned intermediary doctrine. Defendants believe that because Dr. Moore was aware of the data pertaining to the increased risk of suicidality and SSRIs both now and at the time he was prescribing Prozac to Mr. Radke, but would still prescribe Prozac to Mr. Radke if he were alive today, plaintiff cannot meet her burden of proof as a matter of law. Again, the Court disagrees. Dr. Moore's deposition does not indicate that he would continue prescribing Prozac for Mr. Radke had there been adequate warnings pertaining to an increase in suicidality associated with that drug. Instead, Dr. Moore simply states that once the FDA determined that the data was insufficient to prove such a link, he determined that he was "probably not increasing the risk of suicide in [his] depressed patients by using Prozac, but that hopefully, if [he was] doing the right things, [he was diminishing that risk." (Dkt. #115, Ex. U at 112). Given the conditional language of that statement, there appears to be a genuine issue regarding whether a different, increased warning would have persuaded Dr. Moore to take a different course of action with Mr. Radke. Accordingly, the Court finds that the issue of cause in fact must be left to the jury.

Finally, the Court turns to the question of legal causation. In conclusory fashion, defendants argue that logic, common sense, justice, policy and precedent all weigh in favor of awarding defendants summary judgment. However, this Court believes that Washington case law, particularly those cases cited above, supports imposing a duty of manufacturers of generic prescription drugs, just

as it would impose liability on a manufacturer of a reference listed drug if a factfinder determined that it had failed to adequately warn physicians of a particular risk of harm to their patients. Thus, this Court finds that should a jury find causation in fact, liability should attach to defendants.

D. Punitive Damages

Finally, defendant argues that plaintiff's punitive damages request should be dismissed because Washington law prohibits punitive damages in a product liability action. Plaintiff has failed to respond to this argument. Accordingly, the Court deems it unopposed, and will dismiss plaintiff's request for punitive damages.

III. CONCLUSION

Having reviewed defendants' motion for summary judgment, plaintiff's response, defendants' reply, the numerous exhibits and declarations in support of those briefs, and the remainder of the record, the Court hereby finds and ORDERS:

- (1) Defendants' Motion for Summary Judgment (Dkt. #117) is DENIED.
- (2) Any request for punitive damages by plaintiff will be DENIED.
- (3) Defendants' pending Motion to Dismiss (Dkt. #151) and Motion to Exclude Testimony of Witnesses Not Disclosed During Discovery (Dkt. #154) will be addressed in separate Orders.
 - (4) The Clerk shall forward a copy of this Order to all counsel of record.DATED this 31st day of March, 2006.

RICARDO S. MARTINEZ

UNITED STATES DISTRICT JUDGE

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